REMARKS/ARGUMENTS

The Applicant's undersigned patent agent thanks the examiner, Jacqueline Cheng, and supervisor Brian Casler, for discussing issues raised in the Office Action during telephone interviews on or around March 28, 2008.

The terminology of independent Claims 1, 13 and 15 has been amended by way of clarification and to distinguish the invention better from the cited references. Dependent claims have been amended for consistency in terminology and new claims have been added specifying further preferred features of embodiments of the invention.

Thus, as amended, the main claims 1, 13 and 25 now define a method of producing a dosimetry report, and the report itself, in which there is provided a graphical representation comprising:

an image of at least a portion of a body or part of a body that was irradiated during a preceding irradiation interval;

a plurality of graphics artefacts, each representing a radiation sensor positioned in, on or adjacent the body or part thereof during irradiation, the position of each artefact relative to the image corresponding to the position of the corresponding sensor relative to the body or body part, and

a listing of radiation dose measurements each associated with the plurality of identifiers and representing a radiation dose received by a respective one of said sensors during said irradiation interval,

each of said radiation dose measurements being linked visually in the graphics representation with the corresponding one of said graphics artefacts.

Thus, it is clear that a radiation dosimetry report produced according to the present invention contains radiation dose measurements, i.e. for evaluation **after** irradiation, as distinct from data displayed for monitoring and controlling the system operation as exemplified in the cited references.

In paragraph 1 of the Office Action mailed November 28, 2007, the examiner had stated that she disagreed with "applicant's arguments that Ishikawa does not disclose artifacts representing the radiation sensors. Fig. 2 is a *diagram* of a tumor with the sensors, therefore it is not an image taken of the sensors and therefore is an artifact that represents the sensors, not the actual sensors themselves." In fact, applicant had argued that Ishikawa did not

disclose a radiation dosimetry report containing artifacts representing the radiation sensors. During the telephone interview with Mr. Casler, he acknowledged that Fig. 2 of Ishikawa *et al.* does not depict an image in a radiation dosimetry report. He submitted, however, that the paragraph at Column 5, lines 22 to 51 of Ishikawa et al., which preceded the discussion of Fig. 2, might be construed as meaning that Ishikawa *et al.* did, indeed, display an image showing the positions of the dosimeter sensors on an image of the treated body (the tumor), together with their respective readings. Having considered that proposition, even if it were arguable that this paragraph in Ishikawa *et al.* described an image, such as a fluoroscopic map, and superimposed dosimeter positions, the applicant respectfully disagrees that the passage in question discloses all features of the present invention, as set out above, for the reasons given below.

As is known, before a radiation therapy session, for example to irradiate a tumor, a medical physicist will prepare a plan setting out what part of the body is to be irradiated, where the various radiation dosimeter sensors are to be placed, and what radiation dose is to be received by each of the sensors. These are the "target doses". The plan is intended to ensure that the radiation dose applied to the tumor is sufficiently high and the radiation dose experienced by healthy tissue around the tumor is sufficiently low.

With a view to reducing the risk of error when the patient is being prepared prior to the radiation session, for example incorrect location of a particular sensor, the present applicant's granted patent No. 6,650,930 issued November 18, 2003 (of which the present application is a Continuation-in-Part), teaches the use of a graphical representation of the body or body part to be irradiated and icons representing the sensors, the position of each sensor icon relative to the image of the body or body part corresponding to the desired location of the actual sensor relative to the actual body or body part. The procedure is carried out before the radiation session begins.

During the radiation session, each radiation sensor "accumulates" a measurement of the radiation to which it is subjected and, when the session is over, the accumulated doses, i.e., the "actual" radiation dose measurements, are recorded in a radiation dosimetry report. The medical physicist can review the radiation dosimetry report to ensure that the dosimeter sensors were placed according to plan, and determine whether or not the "actual" radiation dose measurements are close enough to the "target" doses. *(See applicant's specification at*

page 3, lines 4-6). Actual radiation dose measurements may differ from target doses for a variety of reasons. If these differences are too great, further irradiation may need to be carried out, perhaps immediately or at a later date.

Hence, in the context of the present invention, a "radiation dosimetry report" according to applicant's claim 1 is a report presenting radiation dose measurements collected during the preceding radiation session for review by, for example, a medical physicist and/or other professional, such as an oncologist.

Just as the present applicant's parent patent US6,650,930 addressed the need for a better way of presenting the information before irradiation of the body or body part to reduce the risk of error, so the present invention addresses the need for a better way of reporting the radiation dose measurements at the various locations after irradiation to facilitate, for example, determination as to whether or not further irradiation is necessary. The present invention addresses that need by means of a radiation dosimetry report in which a graphics representation comprises an image of the irradiated body or body part; graphics artefacts representing the sensors and their locations during the preceding radiation session (or segment thereof); a listing of dose measurements by the sensors, and visual linkage associating each dose measurement with the corresponding sensor, via its graphics artefact in the graphics representation.

Consequently, it is apparent that the cited passage from Column 5, lines 22 to 51 of Ishikawa *et al.* does not describe a method of producing such a radiation dosimetry report. Instead, it describes a procedure for monitoring and controlling the equipment to ensure that the radiation beam is properly applied and, if necessary, re-adjusted by the radiologist. See, in particular, the following statements within that passage:

> "A **short initial registration radiation burst** is used to determine if the radiation beam is in the target area 112 and if the dosage received by the tumor 234 is appropriate."
> "*Each of the one or more transponders 236 and 238 report ... the dosage level it is experiencing* ***during the initial registration burst***".
> "*This information can be* ***displayed ... to confirm that the radiation beam is properly aligned and oriented****, and that the dosage level is within a preset range determined to be appropriate for the particular procedure." [emphasis added]*

It is evident from these statements that Ishikawa *et al.* are describing a monitoring and control procedure. This is clear also from their abstract which states "The system (110) is

controlled and monitored by a CPU (114) which receives instructions from a radiologist operating a control panel (116) and displays **control parameters**, data and graphics to the radiologist on a display (118)" (*emphasis added*). Thus, they do not disclose the production of a radiation dosimetry report which presents the measured radiation doses in a manner which facilitates evaluation of the treatment by a medical physicist after it has been carried out and which can then be stored as a concise reference record.

Thus, Ishikawa *et al.* neither disclose nor suggest the production of a dosimetry report containing, in the same graphics representation, not only an image of at least a portion of a body or part of a body that was irradiated, and graphics artefacts representing the radiation sensors, but also a listing of the radiation dose measurements, each of the said radiation dose measurements being linked visually in the graphics representation with the corresponding one of said graphics artefacts.

In paragraph 5 of the Office Action, the examiner acknowledged that "Ishikawa does not explicitly disclose how this information about each of the radiation dosage the sensors are reading (*sic*) is displayed" and that "It would be obvious to ... use any well known method of displaying information such as such as disclosed by Taylor". With all due respect, the examiner seems to have overlooked the following statement in applicant's specification, in the passage from page 1, line 33 to page 2 line 7:

"The state of the art with patient dose verification systems is for the dose data to be presented in one of three formats – (a) on a display on the reading instrument, (b) on a print-out from the electronic reader or (c) on a computer screen. In the latter case, the information presented on the computer screen is in the form of numbers and, in some cases, graphs.

Thomson & Nielsen MOSFET dosimetry systems use Excel™ spreadsheets for this purpose. Sun Nuclear™ and Scanditronix™ have diode-based systems which use Windows™ – based systems with numerical tables and graphs of data."

A disadvantage of these known systems is that it is not easy to confirm that the dose values measured were taken at the proper locations on the body of the patient.

Thus, in the radiation dosimetry art, these were the "well known methods of displaying information" and, as pointed out by the applicant, they were inadequate. There is no mention in Ishikawa *et al.* or Taylor of the inadequacy of these known methods of displaying dosimetry information in radiation dosimetry reports and no suggestion of the present applicant's solution, which is not surprising given that, as explained above, Ishikawa *et al.* address a

different problem, namely the control and monitoring of the system.

Moreover, Taylor discloses a brachytherapy seed deployment system and the report described in the section cited by the examiner (Figure 7A, column 12 line 65-col.13, line 6) is not a dosimetry report. As stated by Taylor, "FIGS. 7A and 7B illustrate pages 1 and 2 of a **needle loading report**, which will accompany the loaded drape 124" (*emphasis added*). Taylor goes on to say "On page 1 of the needle loading report illustrated at FIG. 7A, the spatial orientation of each needle at the treatment site is identified, as well as the number of radioactive seeds per needle. Page 2 of the needle loading report illustrated at FIG. 7B discloses the precise seed and spacer arrangement for each needle contained in the drape 124". The examiner's statement in paragraph 5 of the Office Action is misleading because Taylor's artifacts do not represent radiation sensors and Taylor's data does not comprise radiation dose measurements. In fact, Taylor's artifacts represent needle locations and his listing of data comprise the number of seeds per needle and the needle coordinates. There is no mention of reporting radiation dose measurements.

Also, attention is directed to the second box at the top of Fig. 7A which refers to a "Pre Operative Plan", i.e., carried out before the radioactive seeds and needles are inserted in a tumor, for accurate treatment delivery. Hence, Taylor makes no reference to the reporting of dose measurements in a dosimetry report enabling a medical physicist to evaluate the irradiation after it has been carried out.

It follows that the examiner's assertions as to what the skilled addressee would find obvious are based upon hindsight culled from reading applicant's specification, rather than upon what is actually taught by the cited references or some other substantive source. [Crown Operations Int'l, Ltd. v. Solutia, Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002)].

Accordingly, the rejection of claims 1, 3, 6-13 and 18-26 under 35 U.S.C. 103(a) as being unpatentable over Ishikawa (US 6,398,710) in view of Taylor (US 6530875) is respectfully traversed on the grounds that *prima facie* obviousness has not been established.

Similar arguments apply to independent claims 13 and 25 directed to the radiation dosimetry reports themselves.

Each of the other claims of record is dependent directly or indirectly upon one or other of claims 1, 13 and 25 and so the rejection of these dependent claims is untenable for at least the same reasons and should be withdrawn.

Moreover, in considering arguments with respect to Jackson, in rejection of claims 2, 4, 5, 14-17 under s.35USC 103(a), the Examiner asserts that Jackson " discloses a post-operative evaluation of the treatment delivery " with reference to Col.11, line 1-35, Fig.8. In fact, Jackson at line 29-31 of column 11 states "The system **calculates** the isodose lines for the actual seed configuration". Thus, it is clear ~~is a~~ that the post-operative evaluation of dose is a purely **mathematical calculation** based on the knowledge of radioactive seeds' radiation characteristics and locations inside a tumor and Fig.8 shows radioactive seed localisation and placement. Thus, Jackson provides a calculated doses, not a target dose nor a measureed dose. No dosimeters are indicated. Jackson provides no teaching of providing a dosimetry report containing dose measurements, and other features as described and claimed in the present application. Consequently, Jackson does not remedy the deficiencies of the disclosures by Ishikawa *et al.* and Taylor in this respect.

Accordingly, the rejection of claims 2, 4, 5, 14-17 , under 35 U.S.C. 103(a) as being unpatentable over Ishikawa *et al.* (US 6,398,710) in view of Taylor (US 6530875) and Jackson Jr. is also respectfully traversed on the grounds that *prima facie* obviousness has not been established.

It is noted that, in paragraph 6 of the Office Action, the examiner discussed the Elliott reference without explicitly applying it in combination with Ishikawa *et al.* and Taylor. Notwithstanding, it is noted that Elliott provides no teaching relating to radiation dosimetry reports as claimed herein, containing dose measurements, and also fail to remedy the deficiencies of the disclosures by Ishikawa *et al.* and Taylor (and Jackson), taken alone or in combination.

In view of the amendments to the independent claims to specify "visual linking", new claims 27 to 30 have been added to specify that the visual linking may comprise lead lines which, in the case of a computer-generated image on a display device, may be adjusted by a user. These new claims are patentable with their antecedent claims for the reasons set out hereinbefore.

In view of the fact that applicant has submitted that the dismissal of the applicant's previous arguments as moot is without foundation, those previous arguments are incorporated herein by reference.

In view of the foregoing, it is submitted that all claims of record are patentable over the

cited references and the applicant respectfully requests withdrawal of the rejection of claims 1 -26, favourable consideration of claims 27to30, and early and favourable reconsideration and allowance of the application.

Respectfully submitted,

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